

Notice of Allowability

Application No.

10/782,285

Examiner

Nyeemah Grazier

Applicant(s)

BRYANS ET AL.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/30/06.
2. ☒ The allowed claim(s) is/are 1-16, 18, 19 and 24.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION
NOTICE OF ALLOWANCE

I. ACTION SUMMARY

The Terminal Disclaimer, Amendments to the Claims, and Remarks submitted to the Office on January 30, 2006 have been fully considered and will be the basis of the following Notice of Allowance.

Claims 1-16, 18-19, and 24 are currently pending. Claim 18, previously withdrawn, has been **rejoined and fully examined** for patentability pursuant to M.P.E.P. § 821.04(b). Claims 17, 20-23, 25 and 26 have been cancelled.

II. RESPONSE TO AMENDMENTS

A. Rejection under 35 USC 112, 2nd Paragraph

Applicant's arguments, see Remarks, filed on January 30, 2006, with respect to rejection of claim 1 has been fully considered and are persuasive in light of the Amendments. The **rejection is obviated.**

B. Double Patenting Rejection (Provisional-ODP)

Applicant's arguments, see Remarks, filed on January 30, 2006, with respect to rejection of claim 19 in view of claim 1 of copending application SN: 10/865,194 has been fully considered and are persuasive in light of the Terminal Disclaimer. The Terminal Disclaimer is approved and the **rejection is obviated.**

C. Claim Objection

Applicant's arguments, see Remarks, filed on January 30, 2006, with respect to claim objection has been fully considered and are persuasive in light of the verbal explanation during a telephonic interview on or about April 6, 2006. The **objection is withdrawn.**

D. Rejoinder of Method and Process Claims

Applicant's arguments, see Remarks, filed January 30, 2006, with respect to the rejoinder of non-elected claims 17 and 18 of Group II and process claim 24 of Group IV has been fully considered and are persuasive.

Claims 1-16 and 19 of Group I are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(b), claim 17 and 18 of Group II and claim 24 of group IV, directed to the process of making or using the allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because a claimed invention previously withdrawn from consideration under 37 CFR 1.142 has been rejoined, **the restriction requirement between groups I and IV and I and II as set forth in the Office action mailed on September 19, 2005 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claims including all the limitations of an allowable product claim or rejoined process claim are presented in a continuation or divisional application, such claims may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35

Art Unit: 1626

U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

III. EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Carl J. Goddard, Esquire on April 6, 2006 and on April 11, 2006.

The application has been amended as follows:

1. Claim 17: **Cancel** claim 17 on page 7 of the Amendment to the Claims.
2. Claim 1: **Delete** “,” and **Insert** ---;--- in claim 1, p. 3, line 14 after “branched C₁₋₆ alkyl”.
3. Claim 16: **Insert** ---and--- after “13-chloro-9-methyl-3-(3, 4, 5, 6-tetrahydro-2H-[1,2']bipyridinyl-4-yl)-2,4,5,9-tetraaza-tricyclo[9.4.0.0*2,6*]pentadeca-1(11),3,5,12,14-pentaene;” at the bottom of p. 6, on line 31.
4. Claim 18: **Delete** “”according to claim 17, wherein the disorder is dysmenorrhoea (primary or secondary), or anxiety.” in claim 18, p. 7, lines 15-17 after “A method”.
5. Claim 18: **Insert** ---of treating a disorder selected from the group consisting of dysmenorrhoea (primary or secondary) and anxiety comprising administering a therapeutically

Art Unit: 1626

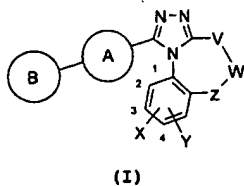
effective amount of a compound according to claim 1 to a patient suffering from such a disorder.--- after “A method” in claim 18, p. 7, line 15.

6. Claim 24: **Delete** “derivative” on line 24, p. 7 after “pharmaceutically acceptable”.

7. Claim 24: **Insert** ---salts, solvates, esters, or amides--- on line 24, p. 7 after “pharmaceutically acceptable”.

IV. REASONS FOR ALLOWANCE

The following is an examiner’s statement of reasons for allowance: The instant invention is drawn to compounds, composition and processes of use and manufacturing the compounds of formula (I) a triazole compound.



The instant invention appears to be free of the art of record. The closest prior art reference of record is Hester et al., “6-Aryl-4H-s-triazolo[4,3-a][1,4]benzodiazepines. Influence of 1-Substitution on Pharmacological Activity,” **J. Med. Chem.**, vol. 22 (11), pp. 1390-98 (1979).

Hester et al. teaches the following:



Art Unit: 1626

The instant invention is free of the art of record because Hester et al. does not teach nor suggest the triazole benzodiazepines substituted by a saturated N-containing heterocycle further substituted by and unsaturated aryl or heteroaryl N-containing ring exemplified as rings A and B in instant formula (I) of the instant invention. Furthermore diazepine moiety of the art of record does not anticipate nor renders obvious the fused ring system having V-W-Z in the instant formula (I).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

V. CONCLUSION

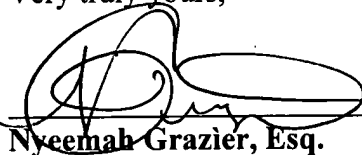
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781. The examiner can normally be reached on Monday through Thursday and every other Friday from 8:30 a.m. - 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Art Unit: 1626

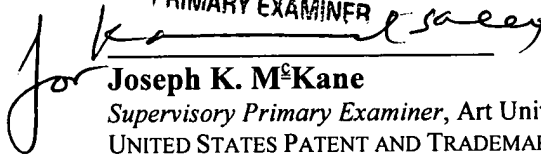
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Very truly yours,



Nyceemah Grazier, Esq.
Patent Examiner, Art Unit 1626
UNITED STATES PATENT AND TRADEMARK OFFICE
400 Dulany Street
Alexandria, VA 22314-5774
Tel. No.: (571) 272-8781

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER



Joseph K. McKane
Supervisory Primary Examiner, Art Unit 1626
UNITED STATES PATENT AND TRADEMARK OFFICE
400 Dulany Street
Alexandria, VA 22314-5774
Tel. No.: (571) 272-0699